IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS U.S.A., INC., *Plaintiff*, v. AMNEAL PHARMACEUTICALS, LLC, *Defendants*.	Civil Action No.: 13-cv-1729-SLR

PLAINTIFF'S REPLY TO DEFENDANT
AMNEAL PHARMACEUTICALS, INC.'S COUNTERCLAIMS

Plaintiff/Counterclaim-Defendant Takeda Pharmaceuticals U.S.A., Inc. ("Takeda") hereby replies the counterclaims asserted by Defendant/Counterclaim-Plaintiff Amneal Pharmaceuticals, Inc. ("Amneal" or "Defendant") as follows:

COUNTERCLAIMS

206. For its counterclaims against Takeda Pharmaceuticals U.S.A., Inc. ("Takeda"), Counterclaimant Amneal Pharmaceuticals LLC ("Amneal") asserts that Amneal's 0.6 mg colchicine product, as described and indicated in amended ANDA No. 20-4711, does not directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, infringe U.S. Pat. Nos. 7,906,519 ("the '519 patent"); 7,395,731 ("the '731 patent"); 8,093,298 ("the '298 patent"); 7,964,648 ("the '648 patent"); 8,093,297 ("the '297 patent"); 7,619,004 ("the '004 patent"); 7,601,758 ("the '758 patent"); 7,820,681 ("the '681 patent"); 7,915,269 ("the '269 patent"); 7,964,647 ("the '647 patent"); 7,981,938 ("the '938 patent"); 8,093,296 ("the '296 patent"); 8,097,655 ("the '655 patent"); 8,415,395 ("the '395 patent"); 8,415,396 ("the '396 patent"); 8,440,721 ("the '721 patent"); and 8,440,722 ("the '722 patent") (collectively "the patents-in-suit"), and/or such patents are invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112. Amneal further asserts that certain of the patents-in-suit are improperly listed in the Orange Book.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

PARTIES

207. Counterclaimant Amneal Pharmaceuticals LLC is a corporation organized under the laws of the State of Delaware, having a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey, 08807-2863. Amneal is in the business of manufacturing, marketing and selling high quality pharmaceutical products in the United States, including the State of Delaware.

ANSWER: On information and belief, Takeda admits the allegations in this paragraph.

208. On information and belief, and as stated by the Plaintiff in its Complaint, Takeda Pharmaceuticals U.S.A., Inc. ("Takeda") is a Delaware corporation with its principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

ANSWER: Admitted.

NATURE OF THE ACTION

209. The counterclaims herein arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq*., the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and under 21 U.S.C. § 355. Amneal seeks entry of a declaratory judgment order that the patents-in-suit are not infringed by Amneal's 0.6 mg colchicine product for the indication described in its amended ANDA, and/or an order that the patents-in-suit are invalid and unenforceable. Further, Amneal seeks entry of an order requiring Takeda to delete the '519, '731, '298, '648, '297, '004, '758, '681, '269, '296, '655, '721, and '722 patents from the listing of patents in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as "the Orange Book") for COLCRYS®.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that Amneal's counterclaims purport to arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq*., the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and under 21 U.S.C. § 355. Takeda denies all remaining allegations in this paragraph. Further, Takeda denies that Amneal is entitled to any of the requested relief and denies that any claim of the patents-in-suit is invalid and/or not infringed.

JURISDICTION AND VENUE

210. This Court has jurisdiction over the asserted counterclaims under 28 U.S.C. §§ 1331, 1337(a) and 1338(a), the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, 35 U.S.C. § 1 *et seq.*, 21 U.S.C. § 355(c)(3)(D) and 21 U.S.C. § 355(j)(5)(c)(ii)(I).

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits only that Amneal's counterclaims purport to arise under 28 U.S.C. §§ 1331, 1337(a) and 1338(a), the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, 35 U.S.C. § 1 *et seq.*, 21 U.S.C. § 355(c)(3)(D) and 21 U.S.C. § 355(j)(5)(c)(ii)(I)

211. Takeda has submitted to personal jurisdiction in this Court by bringing suit against Amneal in this Court. Venue is proper under 28 U.S.C. §§ 1391 and 1400, and as a result of Takeda's choice of forum.

ANSWER: Takeda admits that this Court has personal jurisdiction over it for purposes of this action only.

212. The counterclaims encompass an action based on an actual controversy between Amneal and Takeda concerning the non-infringement and/or invalidity of the patents-in-suit, and/or improper Orange Book listing of certain of the patents-in-suit.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits that there is an actual controversy concerning Amneal's infringement of the patents-in-suit, but denies that Amneal has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

BACKGROUND

213. The patents-in-suit, which are the subject of Amneal's counterclaims, are as follows:

A. The '519 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and a Second Active Agent," with a stated issue date of March 15, 2011, naming on its face Matthew Davis as the inventor.

B. The '731 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics," with a stated issue date of May 11, 2011, naming on its face Matthew Davis as the inventor.

C. The '298 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics," with a stated issue date of January 10, 2012, naming on its face Matthew Davis as the inventor.

D. The '648 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and a Second Active Agent," with a stated issue date of June 21, 2011, naming on its face Matthew Davis as the inventor.

E. The '297 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and a Second Active Agent," with a stated issue date of January 10, 2012, naming on its face Matthew Davis as the inventor.

F. The '519, '731, '298, '648, and '297 patents are collectively referred to herein as the "FMF Patents."

G. The '004 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics," with a stated issue date of November 17, 2009, naming on its face Matthew Davis as the inventor.

H. The '758 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics in the Treatment of Gout Flares," with a stated issue date of October 13, 2009, naming on its face Matthew Davis as the inventor.

I. The '681 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and a Second Active Agent," with a stated issue date of October 26, 2010, naming on its face Matthew Davis as the inventor.

J. The '269 patent is entitled on its face "Methods for Concomitant Administration of Colchicine and a Second Active Agent," with a stated issue date of March 29, 2011, naming on its face Matthew Davis as the inventor.

K. The '647 patent is entitled on its face "Colchicine Compositions and Methods," with a stated issue date of June 21, 2011, naming on its face Matthew Davis as the inventor.

L. The ’938 patent is entitled on its face “Colchicine Compositions and Methods,” with a stated issue date of July 19, 2011, naming on its face Matthew Davis as the inventor.

M. The ’296 patent is entitled on its face “Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics,” with a stated issue date of January 10, 2012, naming on its face Matthew Davis as the inventor.

N. The ’655 patent is entitled on its face “Methods for Concomitant Administration of Colchicine and Macrolide Antibiotics,” with a stated issue date of January 17, 2012, naming on its face Matthew Davis as the inventor.

O. The ’395 patent is entitled on its face “Colchicine Compositions and Methods,” with a stated issue date of April 9, 2013, naming on its face Matthew Davis and Hengsheng Feng as the inventors.

P. The ’396 patent is entitled on its face “Colchicine Compositions and Methods,” with a stated issue date of April 9, 2013, naming on its face Matthew Davis and Hengsheng Feng as the inventors.

Q. The ’721 patent is entitled on its face “Methods for Concomitant Administration of Colchicine and a Second Active Agent,” with a stated issue date of May 14, 2013, naming on its face Matthew W. Davis as the inventor.

R. The ’722 patent is entitled on its face “Methods for Concomitant Administration of Colchicine and a Second Active Agent,” with a stated issue date of May 14, 2013, naming on its face Matthew W. Davis as the inventor.

ANSWER: Admitted.

214. On information and belief, based on statements made by Takeda in its Complaint, Takeda owns the patents-in-suit.

ANSWER: Admitted.

215. On information and belief, based on statements made by Takeda in its Complaint, Takeda owns NDA Nos. 22-351, 22-352 and 22-353 related to colchicine, sold in the U.S. under the name COLCRYS®.

ANSWER: Admitted.

216. On information and belief, the FDA approved Takeda’s NDA No. 22-351 on July 30, 2009, NDA No. 22-352 on July 29, 2009, and NDA No. 22-353 on October 16, 2009.

ANSWER: Admitted.

217. On information and belief, certain patent information purportedly relating to NDA Nos. 22-351, 22-352 and 22-353 is included in the Orange Book; all of the patents-in-suit have been Orange Book listed by Takeda.

ANSWER: Takeda admits only that it caused the patents-in-suit to be listed in the Orange Book as patents "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. §355(b)(1). Takeda denies any remaining allegations in this paragraph.

218. Amneal filed a labeling amendment to its Abbreviated New Drug Application ("ANDA") No. 20-4711 with the United States Food and Drug Administration ("FDA") on September 6, 2013, seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS® for the treatment of FMF, prior to the purported expiration of the patents-in-suit. Amneal provided Takeda with an executed letter ("Amneal's Second Paragraph IV Notice Letter") dated September 9, 2013, providing notice that Amneal had amended ANDA No. 20-4711 seeking marketing approval for a 0.6 mg oral tablet generic version of COLCRYS® for the treatment of FMF, including a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification"), with respect to the FMF patents. In Amneal's Second Paragraph IV Notice Letter, Amneal averred that the FMF patents are invalid and/or are not infringed by Amneal's 0.6 mg oral tablet generic version of COLCRYS® for FMF.

ANSWER: Takeda admits only that it received a letter dated September 9, 2013 and signed by a representative of Amneal (the "September Notice Letter"). The September Notice Letter stated that it was providing "notice of Paragraph IV certification of invalidity and/or non-infringement concerning U.S. Patent Nos. 7,06,519, 7,935,731, 8,093,298, 7,964,648 and 8,093,297." Takeda denies any remaining allegations in this paragraph.

219. Takeda filed a patent infringement Complaint against Amneal in this Court on October 21, 2013, alleging infringement of the FMF patents, and on September 4, 2014, Takeda filed an Amended Complaint alleging infringement of the patents-in-suit.

ANSWER: Admitted.

220. Amneal has denied and denies that it has infringed, currently infringes or will infringe, directly or indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, any valid and enforceable claim of the patents-in-suit. Amneal has further asserted and asserts that the claims of the patents-in-suit are invalid for failure to satisfy one or more of

the provisions of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103 and/or 112.

ANSWER: Upon information and belief, Takeda admits that Amneal has denied that it has, is, or will infringe the patents-in-suit and that Amneal asserts that the patents-in-suit are invalid. Takeda denies that Amneal has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

221. Based on Takeda's filing of the Complaint, and Amneal's denial of Takeda's claims and Amneal's assertion of affirmative defenses, an actual controversy exists between the parties as to whether Amneal has infringed, is currently infringing or will infringe any valid and enforceable claim of the patents-in-suit, whether any of the patents-in-suit are valid, and whether certain of the patents-in-suit have been improperly listed in the Orange Book.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits that there is an actual controversy concerning Amneal's infringement of the patents-in-suit, but denies that Amneal has any valid claim of noninfringement or invalidity. Takeda denies any remaining allegations in this paragraph.

FIRST COUNTERCLAIM
Declaratory Judgment of Non-Infringement of the Patents-in-Suit

222. Amneal repeats and realleges paragraphs 206-221 as if fully set forth herein.

ANSWER: Takeda repeats and incorporates by reference its responses to paragraphs 206-221 as if fully set forth herein.

223. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the '519 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

224. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ’731 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

225. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ’298 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

226. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ’648 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

227. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ’297 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

228. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ’004 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

229. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ’758 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

230. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ’681 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

231. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ’269 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

232. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ’647 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

233. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ’938 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

234. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ’296 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

235. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ’655 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

236. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ’395 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

237. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ’396 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

238. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ’721 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

239. Amneal has not infringed, does not currently infringe, and will not infringe any valid and enforceable claim of the ’722 patent directly, indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

SECOND COUNTERCLAIM
Declaratory Judgment of Invalidity of the Patents-in-Suit

240. Amneal repeats and realleges paragraphs 206-239 as if fully set forth herein.

ANSWER: Takeda repeats and incorporates by reference its responses to paragraphs 206-239 as if fully set forth herein.

241. Each and every claim of the ’519 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

242. Each and every claim of the ‘731 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

243. Each and every claim of the ’298 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

244. Each and every claim of the ’648 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

245. Each and every claim of the '297 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

246. Each and every claim of the '004 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

247. Each and every claim of the '758 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

248. Each and every claim of the ’681 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

249. Each and every claim of the ’269 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

250. Each and every claim of the ’647 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

251. Each and every claim of the ’938 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

252. Each and every claim of the ’296 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

253. Each and every claim of the ’655 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

254. Each and every claim of the ’395 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

255. Each and every claim of the ’396 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

256. Each and every claim of the '721 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

257. Each and every claim of the '722 patent is invalid for failing to comply with one or more of the provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

THIRD COUNTERCLAIM
Delisting of the '519, '731, '298, '648, '297, '004, '758, '681, '269, '296, '655, '721 and '722 Patents

258. Amneal repeats and realleges paragraphs 206-257 as if fully set forth herein.

ANSWER: Takeda repeats and incorporates by reference its responses to paragraphs 206-257 as if fully set forth herein.

259. 21 U.S.C. § 355(j)(5)(c)(ii)(I) provides an ANDA holder with a counterclaim cause of action to seek an order requiring an NDA holder to delete patent information in an Orange Book listing on the ground that the patent does not claim either the drug for which the NDA was approved or an approved method of using the drug.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

260. COLCRYS® has been approved by the FDA as a single-ingredient oral colchicine product for the following indications:

- Prophylaxis and Treatment of Gout Flares in adults and
- Familial Mediterranean fever (FMF) in adults and children 4 years or older.

ANSWER: Admitted.

261. COLCRYS® has been approved by the FDA with the following dosage and administration regimen:

- Gout Flares:

  Prophylaxis of Gout Flares: 0.6 mg once or twice daily in adults and adolescents older than 16 years of age. Maximum dose 1.2 mg/day. Treatment of Gout Flares: 1.2 mg (2 tablets) at the first sign of a gout flare followed by 0.6 mg (1 tablet) one hour later.

- FMF: Adults and Children older than 12 years 1.2 – 2.4 mg; Children 6 to 12 years 0.9 – 1.8 mg; Children 4 to 6 years 0.3 – 1.8 mg.
  - Give total daily dose in one or two divided doses.
  - Increase or decrease the dose as indicated and as tolerated in increments of 0.3 mg/day, not to exceed the maximum recommended daily dose.

ANSWER: Admitted.

262. The FDA approved usage codes for COLCRYS® are as follows:

U-1007: Method of Treating Gout Flares;

U-1020: Method for Using Colchicine for the Prophylaxis of Gout Flares;

U-1116: Method of Administering Colchicine to Familial Mediterranean Fever Patients;

U-1161: For the Treatment and Prophylaxis of Gout Flares & the Treatment of Familial Mediterranean Fever; and

U-1166: A Method for Treatment of Gout Flares during Prophylaxis.

ANSWER: Admitted.

263. Takeda has listed the ’519, ’731, ’298, ’648, ’297, ’004, ’758, ’681, ’269, ’296, ’655, ’721 and ’722 patents in the Orange Book in relation to NDA Nos. 22-351, 22-352 and 22-353 and its colchicine product, sold in the U.S. under the name COLCRYS®.

ANSWER: Takeda admits only that it caused the ’519, ’731, ’298, ’648, ’297, ’004, ’758, ’681, ’269, ’296, ’655, ’721, and ’722 patents to be listed in the Orange Book as patents “with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” 21 U.S.C. §355(b)(1). Takeda denies any remaining allegations in this paragraph.

264. The claims of each of the ’519, ’731, ’298, ’648, ’297, ’004, ’758, ’681, ’269, ’296, ’655, ’721 and ’722 patents recite methods for the concomitant administration of colchicine and a drug other than colchicine.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda admits that certain claims of the ’519, ’731, ’298, ’648, ’297, ’004, ’758, ’681, ’269, ’296, ’655, ’721 and ’722 patents recite methods for the concomitant administration of colchicine and a drug other than colchicine.

265. No claim of the ’519, ’731, ’298, ’648, ’297, ’004, ’758, ’681, ’269, ’296, ’655, ’721 and ’722 patents covers the drug colchicine or an approved method of using COLCRYS®, based on the FDA approved indications, the approved dosage and administration statements and the usage codes stated for COLCRYS®.

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

266. The listing of the ’519 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

267. The listing of the ’731 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

268. The listing of the ’298 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

269. The listing of the ’648 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

270. The listing of the ’297 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

271. The listing of the ’004 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

272. The listing of the ’758 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

273. The listing of the ’681 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

274. The listing of the ’269 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

275. The listing of the ’296 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

276. The listing of the ’655 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

277. The listing of the ’721 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

278. The listing of the ’722 patent in the Orange Book for COLCRYS® should be immediately deleted under 21 U.S.C. § 355(j)(5)(c)(ii)(I).

ANSWER: This paragraph contains legal conclusions to which Takeda believes no response is required. To the extent a response is required, Takeda denies the allegations in this paragraph.

AMNEAL’S DEMAND FOR JUDGMENT

To the extent that this section may be deemed to allege any facts or factual or legal entitlements to the relief requested, Takeda denies each and every such allegation. Specifically, Takeda denies that Amneal is entitled to any of the requested relief, including recovery for attorneys’ fees and costs.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff/Counterclaim-Defendant Takeda respectfully requests this Court to enter judgment against Defendant/Counterclaim-Plaintiff Amneal Pharmaceuticals, Inc. as follows:

A. dismissing Defendant Amneal's counterclaims with prejudice;

B. finding that this is an exceptional case and granting Takeda reasonable attorney's fees pursuant to 35 U.S.C. § 285;

C. awarding Takeda the relief requested in its Complaint; and

D. awarding Takeda any further and additional relief as this Court deems just and proper.

Date: October 6, 2014

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CERTIFICATE OF SERVICE

I hereby certify that on October 6, 2014, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on October 6, 2014, upon the following individuals via electronic mail:

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